Annexure - II(b)
Details of clinical trial Permissions (Form CT-06)
Year 2021

S.No.	File No.	Firm Name	Name of Product	Phase	Title of the study	Permission No.	Date of Issue	Summary
1	BIO/CT/20/000178	M/s Bharat Serums And Vaccines Limited, 17th Floor, Hoechst House, Nariman Point Mumbai (India) – 400 021	Equine COVID 19 Antiserum (Liquid Injection)	Phase I/II	A Prospective, Randomized, Multi-center, Open label, Phase 1/2 study to Evaluate the Safety and Efficacy of Equine COVID-19 Antiserum [F(ab')2] (BSVEQAb) plus Standard of Care in Comparison to Standard of Care alone in COVID-19 RT-PCR positive Patients" vide Protocol no. BSV_EQ AB_20_08, Version 02 dated 30.12.2020	CT- 01/2021	20-01-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 17.12.2020 CT permission was granted.
2	BIO/CT/20/000182	M/s Gennova Biopharmaceuticals Limited, Emcure House, T-184, MIDC, Bhosari, Pune, Maharashtra, – 411 026	mRNA Vaccine for Injection(COVID-19)	Phase I/II	The phase I/II clinical trial should be conducted as per protocol no. GBL/HGCO19/2020/01 Version 1.0 dated 11.11.2020 subject to the conditions as mentioned under this permission	CT- 02/2021	25-01-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 09.12.2020 CT permission was granted.
3	BIO/CT/20/000186	M/s Serum Institute of India Pvt. Ltd., S. No. 105- 110, Manjari Bk. Pune (lndia) - 412307	SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine	Phase II/III	"A phase 2/3, observer blind, randomized, controlled study to determine the safety and immunogenicity of COVOVAX [SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1™ adjuvant] in Indian adults	CT- 03/2021	11-02-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 03.02.2021 CT permission was granted.
4	BIO/CT/21/000001	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078	Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154)	Phase I	"A Phase 1, Randomized, Double-blinded, Multicenter Study to Evaluate the Reactogenicity, Safety, and Immunogenicity of an Intranasal Adenoviral vector COVID-19 vaccine (BBV154) in Healthy Volunteers" vide Protocol No: BBIL/BBV154/2020 Version No: 2.0; Date: 20-01-2021	CT- 04/2021	12-02-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 03.02.2021 CT permission was granted.

5	BIO/CT/20/000071	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)	Phase III	A single blind randomised active-controlled Phase-III study to evaluate safety and immunogenicity of a candidate 14- valent pneumococcal polysaccharide conjugate vaccine administered to 6-8 weeks old healthy Indian Infants in 6-10 -14 weeks dosing schedule" vide Protocol No.: BECT061/PCV Phase-III/CTP-01, Version No.: 1.0 Final dated 14.05.2020"	CT- 05/2021	05-03-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06.07.2020 CT permission was granted.
6	BIO/CT/21/000009	M/s Cadila Healthcare Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej-Bavla, N.H. No. 8A, Village-Changodar, Taluka - Sanand, Dist. Ahmedabad - 382 213	Novel Corona virus-2019-nCoV Vaccine	Phase I/II	"A prospective, randomized, phase I/II clinical study to evaluate the safety and immunogenicity of 3mg dose of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects " protocol no.: project no. 21-01 version No. 01 dated 17- 02-2021	CT- 06/2021	15-03-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 03.02.2021 CT permission was granted.
7	BIO/CT/20/000187	M/s Tergene Biotech Private Limited ,Suite 121 & 122, Building 450, Genome Valley, Turkapally (V), Shamirpet (M), RR Dist, HYDERABAD (India) - 500078	Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed), I.P. (15 valent)	Phase III	A Phase 3, Observer blind, Randomized, Active-Controlled Trial Evaluating the Immunologic Non-inferiority, Safety and Tolerability of a 15-valent Pneumococcal Conjugate Vaccine Compared to a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given with Routine Pediatric Vaccinations" & Protocol Number –CBCC/2020/029, Version number:1.0, 09/Nov/2020. II. The firm is required to constitute a DSMB to review the safety data.	CT- 07/2021	26-03-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 04.02.2021 CT permission was granted.

8	BIO/CT/21/000051	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	Covid-19 vaccine containing Receptor Binding Domain of SARS CoV-2 (RBD antigen of SARS CoV-2 (Cov	Phase III	"A Prospective, Open-label, Single-arm, Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Biological E's SARS-CoV-2 COVID-19 Vaccine for Protection Against COVID-19 Disease when administered to COVID-19-negative adult subjects" vide protocol no. BECT/COVID-19-PHASE III/069 version 1.0 dated 14-APR-2021	CT- 08/2021	23-04-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 20.04.2021, CT permission was granted.
9	BIO/CT/21/000055	M/s. Hetero Limited, H. No. 8-3-166/1 & 2, 105 To 108, 1st Floor, G Block, East Wing, Challa Estates, Erragadda, Hyderabad (India) - 500018	Gam-COVID-Vac combined vector vaccine (Component I & Component II)	Phase III	"A Prospective, Randomized, Interventional, Parallel, Multi-Center, Comparative Clinical Trial to Evaluate the Safety and Immunogenicity of COVID-Vac Combined Vector Vaccine (Manufactured by Hetero) in Healthy Adult Human Subjects" & Protocol Number– HCR/III/SARSCOV2VAC/04/2021, Version:2.0, dated 24.04.2021.	CT- 09/2021	27-04-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 23.04.2021 CT permission was granted.
10	BIO/CT/21/000004	M/s JSS Medical Research India Private Limited, Plot No. 12/2, 6th Floor, Vatika Mindscapes, Tower-B, Sector-27 D, Faridabad (India) -121003	Equine Anti Covid Antibody Fragments F(ab') 2	Phase I/II	"A prospective, randomized, multicentric, comparative Phase I/ Phase II clinical trial to evaluate the clinical safety, efficacy and tolerability of Equine Anti Covid Antibody Fragments F(ab')2 as an add on therapy to Standard of Care (SOC) in comparison to SOC alone in hospitalized adult subjects with COVID-19 infection, with moderate severity", protocol no. VBP-EAF-001 version 4.0 dated 27 Apr 2021.	CT- 10/2021	05-05-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 23.04.2021 CT permission was granted.
11	BIO/CT/20/000138	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078	Purified, Inactivated Japanese Encephalitis Vaccine IP	Phase III	A Phase III, Open Label to evaluate safety and immunogenicity in healthy volunteers followed by non-interference immune response study of inactivated Japanese encephalitis vaccine (JENVAC) when co-administered with Measles, Mumps and Rubella (MMR) Vaccine. Vide Protocol No: BBIL/JENVAC/2021, Version No: 2.0 dated: 04-02-2021	CT- 11/2021	13-05-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 04.02.2021. CT permission was granted.

12	BIO/CT/21/000021	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078	Whole Virion Inactivated Corona Virus Vaccine, [BBV152]	Phase II/III	A Phase II/III, Open Label, Multicenter Study to Evaluate the Safety, Reactogenicity and Immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 Vaccine (COVAXIN®) in Healthy Volunteers ages ≤18 to ≥ 2 Years. Protocol No: BBIL/BBV152/2021 Version No:2.0; Date: 17-04-2021.	CT- 12/2021	12-05-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 24.02.2021 CT permission was granted.
13	BIO/CT/20/000135	M/s Techinvention Lifecare Pvt Ltd, 702, Samarpan Complex, New Link Road Chakala, Andheri East, Mumbai Mumbai (India) - 400099	Oral Cholera Vaccine (Inactivated)	Phase III	A Phase III, open label, multicenter, parallel group, randomized Clinical Study to compare the Immunogenicity and Safety of Euvichol-Plus vaccine with Oral Cholera Vaccine ShancholTM in healthy adults and children above age of one year" [Protocol: EPV/TLC/P-III/2020, Version No.:2.0, Date: 7th March 2021]".	CT- 13/2021	20-05-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 10.02.2021 CT permission was granted.
14	BIO/CT/21/000038	M/s Urihk Pharamceutical Pvt. Ltd. 602-603, Sai Samarth Park, Near Wasan Motors, Deonar Village Road, Deonar, Govandi (East) Mumbai (India)-400088 (Note: Earlier, granted to M/s Wockhardt and later on transfer of sponsor to M/s Urihk.	Recombinant Hepatitis E Vaccine (E.Coli)	Phase III	A Prospective, Randomized, Double Blind, Placebo controlled Phase III, Multicenter study to evaluate the Immunogenciity and Safety of Recombinant Hepatitis E Vaccine in Healthy Adults & Adolescents, Protocol: URI/HEV/CT-01/21, Version: 01 dated: 24-02-2021	CT- 14/2021	19-05-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 12.11.2018 CT permission was granted
15	BIO/CT/20/000065	M/s Cadila Pharmaceuticals Limited, 1389-Trasad Road Dholka Dholka (India) - 387810	Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle)	Phase III	Double Blind" as per SEC (Vaccine) recommendations dated 04-Feb-2021 and the remaining protocol should be as per the protocol no. CRSC20002, version no.: 2.0, dated 20th April, 2021	CT- 15/2021	03-06-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 04.02.2021 CT permission was granted.
16	BIO/CT/20/000149	M/s Indian Immunological Limited, Rakshapuram, Gachibowli post Hyderabad Rangareddi Hyderabad-500032, India	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents IP	Phase II/III	A Phase II/III Multicentric Randomized Single Blind Study to Compare the Immunogenicity and Safety of Diphtheria and Tetanus vaccine (Adsorbed) for Adults and Adolescents (Td vaccine) of HBI with BE Td® Vaccine in two age groups of Healthy Subjects". Protocol no.: HBI/Td/II/III/2020/002.01.01 Dated: 05 April 2021	CT- 16/2021	02-06-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.03.2021 CT permission was granted.

17	BIO/CT/20/000137	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078	Chikungunya vaccine (Inactivated)	Phase II/III	A Seamless Phase II/III, Double-blind, Multi-centre, Randomized Clinical Trial to Evaluate Immunogenicity and Safety of BBV87, an Inactivated Chikungunya Virus Vaccine in Healthy Subjects 12-65 Years of Age" vide Protocol No: BBIL/CHIKV/II-III/2019 Version No: 1.0 Date: 30-07-2020	CT- 17/2021	04-06-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 30.09.2020 CT permission was granted.
18	BIO/CT/21/000059	M/s Premium Serums And Vaccines Pvt. Ltd., 406, B Wing, Highway Rose Co-op. Housing Society 92, Dixit Road Extn., Vile Parle (East), Mumbai (India) - 400057	Anti-COVID19 Serum [Equine Anti Covid Antibody Fragments F(ab')2]	Phase I	A Phase I, Randomized, Controlled, Open Label Study to Assess the Safety and Efficacy of COVID-19 Antiserum in Adult Patients with SARS-CoV-2/COVID-19 Disease" vide protocol no. SII-COVID19- EqS/IN-01, version no. 3 dated 17.05.2021	CT- 18/2021	09-06-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 27.05.2021 CT permission was granted.
19	BIO/CT/21/000069	M/s Virchow Biotech Private Limited, Plot No. 4 S.V.Co-op. Industrial Estate Jeedimetla (India) - 500055	Gam-COVID-Vac combined vector vaccine (Component I & Component II)	Phase III	A Randomized, Multi-Center, Phase III Comparative Clinical Trial to Evaluate the Safety and Immunogenicity of Virchow Biotech Manufactured VB-COVIDVAC Combined Vector Vaccine in Healthy Adult Human Subjects" Protocol No: VB-COVIDVAC/2021-CT1; Version: 1; Version Date: 01.05.2021	CT- 19/2021	09-06-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 01.06.2021 CT permission was granted.
20	BIO/CT/21/000073	M/s. Axis Clinicals Limited, 1-121/1 Miyapur Hyderabad (India) - 500049	1. Multitope Protein/ Peptide-Based SARS-CoV-2 Vaccine (Manufactured by M/s Aurobindo Pharma Limited, Hyderabad) 2. UB-612(Imported from M/s UBI Pharma (UBIP),Taiwan)	Phase II/III	A Phase 2/3 Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Immunogenicity, and Efficacy of COVID-19 Vaccine UB-612 in Adults" vide protocol no. UB-612-302, Version: 1.1; Version Date: 15.06.2021.	CT- 20/2021	28-06-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 01.06.2021,02.06.2021 and 03.06.2021 CT permission was granted.
21	BIO/CT/21/000079	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078	Coronavirus vaccine (rDNA) – BBV151	Phase I	A Phase I, Open label, Dose escalation, Randomized, Multicenter Study to Evaluate the Reactogenicity, Safety, and Immunogenicity of an Intramuscular inactivated rabies vector platform Corona Virus Vaccine (rDNA-BBV151) in Healthy Volunteers" vide protocol no. BBIL/BBV151/2021, version no. 1.0 dated 05-06-2021	CT- 21/2021	09-07-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 14.06.2021 CT permission was granted.

22	BIO/CT/21/000044	M/s G. C. Chemie Pharmie limited, 5/C, Shree Laxmi Indl. Estate, New Link Road, Andhderi (West), Mumbai – 400 053	23-valent Pneumococcal Polysaccharide Vaccine I.P.	Phase III	A Randomized, Double blinded, Multicenter Phase III Clinical Trial to Evaluate the Immunogenicity and Safety of 23- Valent Pneumococcal Polysaccharide Vaccine in Healthy Adults" vide protocol number: CRN_India/ 2711/2020, version no. 1.0 dated 20-Oct-2020.	CT- 22/2021	16-07-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 10.02.2021 CT permission was granted.
23	BIO/CT/20/000079	M/s Serum Institute of India Pvt. Ltd. (SIIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028, India	VPM1002 (rBCG) Vaccine	Phase III	A Multicenter, Phase III, Double-blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of VPM1002 Vaccine in the Prevention of Tuberculosis Infection in Health Care Workers" vide Protocol Number: VPM1002-HCW Version: 2.0 dated 27Apr 2021	CT-23/2021	16-07-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.03.2021 CT permission was granted.
24	BIO/CT/21/000092	M/s Christian Medical College, Ida Scudder Road, Vellore- 632004, Tamil Nadu	Whole Virion Inactivated Corona Virus Vaccine, [BBV152] (COVAXIN), ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (COVISHIELD)	Phase IV	"Comparison of reactogenicity and immunogenicity of heterologous prime- boost and heterologous boost of ChAdOx1 nCoV-19 (Covishield), BBV152 (COVAXIN) and other COVID vaccines with homologous administration of COVISHIELD and COVAXIN" vide Protocol No: Mixing of COVID vaccines study, Version: 1.0 Date: 10th July 2021.	CT- 24/2021	07-08-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 29.07.2021 CT permission was granted.
25	BIO/CT/21/000077	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078	Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154)	Phase II	A Phase 2, Randomized, Double Blind, Multicenter Study to Evaluate the Immunogenicity, Reactogenicity and Safety of an Intranasal Adenoviral vector COVID-19 vaccine Healthy Volunteers." vide Protocol No: BIL/BBV154-II/2021 Version No: 3.0; Date: 07-08-2021.	CT- 25/2021	08-08-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 22.06.2021 CT permission was granted.
26	BIO/CT/21/000096	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078	Whole Virion Inactivated Corona Virus Vaccine, [BBV152] (COVAXIN), Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154)	Phase II	A Phase 2 randomized, multi-centric, Clinical Trial of Heterologus Prime-Boost Combination of SARS-CoV-2 Vaccines to evaluate the immunogenicity and safety of BBV152 (COVAXIN®) with BBV154 (Adenoviral Intranasal COVID-19 vaccine) in Healthy Volunteers."	CT- 26/2021	11-08-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 29.07.2021 CT permission was granted.

27	BIO/CT/21/000102	M/s Dr Reddy's Laboratories Limited, IPDO, Survey no 54 Bachupally Vilage Qutubullapur Mandal (India) - 500090	A vector vaccine for the prevention of the coronavirus infection induced by the SARSCoV-2 virus - (Sputnik Light)	Phase III	"Phase III, open label, un-controlled, multicentre, bridging study to evaluate immunogenicity and safety of single dose of Sputnik Light in Indian adults and elderly for prevention of SARS-CoV-2 Infection" Protocol No DRL SPL-005 Date of Protocol Version 2.0 dated 09 Aug 2021.	CT- 27/2021	16-08-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06.08.2021 CT permission was granted.
28	BIO/CT/21/000103	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19)	Phase III	A Prospective, Single-blind, Randomized, Active-controlled Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Biological E's CORBEVAX Vaccine for Protection Against COVID-19 Disease When Administered to RT-PCR Negative Adult Subjects." vide protocol no. BECT/COVID-19-PHASE-III/074.	CT- 28/2021	20-08-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 19.08.2021 CT permission was granted.
29	BIO/CT/21/000105	M/s Gennova Biopharmaceuticals Limited ,T-184 emcure house bhosari MIDC pune pune (India) - 411026	HGCO19 Lyophilized mRNA Vaccine for Injection (COVID 19)	Phase II/III	A Prospective, Multicentre, Randomized, Active-controlled, Observerblind, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability and Immunogenicity of the candidate HGCO19 (COVID-19 vaccine) in healthy subjects." vide protocol no. GBL/HGCO19/2021/01 Version 1.1 Dated 21 Aug 2021.	CT- 29/2021	22-08-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 19.02.2021 & 22.08.2021 CT permission was granted.
30	BIO/CT/21/000089	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	SARS-CoV-2 (Covid-19) Vaccine (RBD antigen of SARS CoV-2 (Covid-19)	Phase II/III	A Prospective, Randomised, Double-blind, Placebo controlled, Phase-II by III Study to Evaluate Safety, Reactogenicity, Tolerability and Immunogenicity of CORBEVAX Vaccine in Children and Adolescents" vide protocol no. BECT072/Covid-19-phase-II&III/CTP-01, Version no. 1.1 dated 11.08.2021.	CT- 30/2021	01-09-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.08.2021 CT permission was granted.
31	BIO/CT/21/000108	M/s Reliance Life Sciences, Center, R-282, TTC Area of MIDC, Thane -Belapur Road, Rabale, Navi Mumbai (India) – 400 701	Protein subunit vaccine against SARS-CoV-2 Virus	Phase I	A prospective, open label, dose escalation phase I clinical study to evaluate the safety, tolerability and immunogenicity of Reliance Life Sciences SARS-CoV-2 Recombinant protein subunit vaccine in healthy volunteers" as per protocol no. RLS/VAC/2021/07.	CT- 31/2021	03-09-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 26.08.2021 CT permission was granted.

32	BIO/CT/21/000062	M/s Cadila Healthcare Limited, plot survey no. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213	Typhoid Vi Conjugate Vaccine I.P.	Phase III	A prospective, randomized, two-arm, parallel, active-controlled, multicentre, non-inferiority, phase III clinical trial to evaluate the immunogenicity and safety of ZyVac TCV of M/s Cadila Healthcare Limited compared to Typbar TCV of M/s Bharat Biotech International Limited in healthy adults aged 45 to 65 years" vide protocol no. 21-03, version 01 dated 17.08.2021	CT- 32/2021	08-09-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06.08.2021 CT permission was granted.
33	BIO/CT/21/000084	M/s Glaxosmithkline Pharmaceuticals Limited, 252, Dr. Annie Besant Road, Worli, Mumbai-400030, Maharashtra, India. Mumbai (India) - 400030	Herpes Zoster Vaccine (Recombinant, Adjuvanted)	Phase III	A phase 3, randomised, observer blind, placebo-controlled, multi-centre study to evaluate the immune response and safety of the Herpes Zoster subunit vaccine when administered intramuscularly on a 2-dose schedule in adults aged 50 years and older in India" as per Protocol No.: 214461 (ZOSTER-081), Version No. 01, Dated 08-June-2021	CT- 33/2021	16-09-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06.08.2021 CT permission was granted.
34	BIO/CT/21/000134	M/s Cadila Healthcare Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej-Bavla, N.H. No. 8A, Village-Changodar, Taluka - Sanand, Dist. Ahmedabad - 382 213	Novel Corona virus-2019-nCoV Vaccine (recombinant)	Phase III	A prospective, open-label, single arm, multicenter, phase III clinical study to evaluate the immunogenicity and safety of 3mg (2 dose) regimen of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects Project No.:21-103.Amendment No.:01 dated 17.09.2021.	CT- 34/2021	30-09-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 23.09.2021 CT permission was granted.
35	BIO/CT/21/000065	M/s Sanofi Healthcare India Private Limited Sanofi House, C.T.S-117B, L & T Business Park, Saki Vihar Road, Powai Mumbai – 400072, Maharashtra.	Quadrivalent Influenza vaccine (Split Virion, Inactivated)	Phase III	" Immunogenicity and Safety of the Quadrivalent Inactivated Split-Virion Influenza Vaccine in Participants 6 Months of Age and Older in India." [Study Code: GQM00023, Protocol Version Number: 2.0, Dated 22-February-2021	CT- 35/2021	12-10-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06/08/2021 CT permission was granted.

36	BIO/CT/21/000074	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (r-DNA) and Haemophilus influenza type b Conjugate Vaccine (Adsorbed)	Phase IV	"A prospective open label comparative phase-IV bridging study to assess the equivalence of the revised DTwP rHepB-HIB vaccine formulation with that of the currently licensed DTwP-rHepB-HIB formulation in 6-8 weeks old infants" vide protocol no. BECT068/LPV-PIV-Bridging/CTP-01, Version no. 1.0 dated 26.03.2021.	CT- 36/2021	12-10-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06.08.2021 CT permission was granted.
37	BIO/CT/21/000130	M/s Cadila Healthcare Limited, plot survey no. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213	Typhoid Vi Conjugate Vaccine I.P.	Phase IV	An active post-marketing surveillance study to evaluate the safety and immunogenicity of ZyVac TCV of M/s Cadila Healthcare Limited in healthy subjects" vide protocol no. 21-09, version 00 dated 20.08.2021	CT- 37/2021	13-10-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.09.2021 CT permission was granted.
38	BIO/CT/21/000032	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	Inactivated Hepatitis A Vaccine (Adsorbed)	Phase I	A prospective open label single arm phase-I study to assess the safety, tolerability, reactogenicity and immunogenicity of a single intramuscular dose of BE's indigenously developed inactivated Hepatitis A vaccine (adsorbed) administered to 18-45 years old healthy human adults.[Protocol no: BECT067/HepA-Phase-I/CTP-01, Protocol Version 1.0, dated 27.01.2021	CT- 38/2021	21-10-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.03.2021 CT permission was granted.
39	BIO/CT/21/000033	M/s Ra (biologicals) Panacea Biotec Ltd., A-27, B-1 Extension Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (11-valent)	Phase I	A Randomized, Open label, Multicenter, Phase II/III study to assess and compare the immunogenicity and safety of NUCOVAC®-11 {Pneumococcal Polysaccharide conjugate vaccine (Adsorbed), 11 valent}of Panacea Biotec Ltd. with PREVENAR13®of Pfizer Inc.in healthy infants (3+1immunization schedule) [Protocol no: PBL/20/01/PNCV, Version Number: 03, Dated 31-July-2021].	CT- 39/2021	22-10-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 31.03.2021 CT permission was granted.

40	BIO/CT/21/000060	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	Typhoid Conjugate Vaccine (Monovalent) [Typhoid Vi Conjugate Vaccine]	Phase IV	A prospective multicentre phase-IV clinical study to evaluate the safety of single intramuscular dose of Biological E's typhoid conjugate vaccine in 6 months to 45 years old participants and its impact on measles immunogenicity when co-administered with licensed Measles-Rubella (MR)vaccine in a subset of 9-12 months old infants" vide protocol no. BECT064TCVPhase IV version 1.1 dated 20.09.21.	CT- 40/2021	01-12-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 06.08.2021 CT permission was granted.
41	BIO/CT/21/000097	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	Measles (Edmonston Zagreb) and Rubella (RA27/3) Vaccine Live, Attenuated (Freeze Dried), IP	Phase I	A Phase I Open Label Study to Evaluate the Safety, Tolerability and Immunogenicity of Biological E's Live, Attenuated Measles Rubella Vaccine (MR) in 4-5 year Old Healthy Children" vide protocol no. BECT073/MRV-PI/CTP-01, version no: 01, dated 10/07/2021	CT- 41/2021	28-12-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.09.2021 CT permission was granted.
42	BIO/CT/21/000142	M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) - 500078	SARS-CoV-2 (Covid-19) Vaccine (RBD antigen of SARS CoV-2 (Covid-19))	Phase III	A Prospective double-blind randomised Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Single Booster dose of Biological E's CORBEVAX vaccine when Administered to COVID-19-Negative Adult Volunteers Previously vaccinated with 2-doses of either COVISHIELD or COVAXIN" vide protocol no. BECT/COVID-19-PHASE-III/070.	CT- 42/2021	28-12-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 27.12.2021 CT permission was granted.
43	BIO/CT/21/000133	M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078	Cholera Vaccine (Inactivated, Oral), I.P	Phase III	A Phase III randomized, modified double-blind, multi-centric, comparative study, to evaluate the non-inferiority of immunogenicity and safety of single strain oral cholera vaccine Hillchol® to the comparator vaccine Shanchol™ along with lot-to-lot consistency of Hillchol®." vide Protocol No: BBIL/BBV-Hillchol®(BBV131)/2021 Version No: 2.0; Date: 21-Sept-2021	CT- 43/2021	31-12-2021	Based on review of documents submitted and the recommendations of Subject Expert Committee (SEC) meeting dated 21.09.2021 CT permission was granted.